K082599
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OCT 17 2008

CNSystems
The Brain & Heart Company

CNSystems CNAP Monitor 500 Traditional 510(k) Filing

510(k) Summary (per 21 CFR 807.92)

Name of Submitter:	CNSystems Medizintechnik AG Reininghausstrasse 13, A-8020 Graz, Austria
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Date prepared:	February 18, 2008
Trade names:	Non-invasive continuous blood pressure monitoring system CNAP Monitor 500i, 500ac
Classification:	Class II
Classification name:	21 CFR 870.1130, System, measurement, blood pressure, non-invasive, DXN
Predicate:	The CNAP Monitor 500 is substantially equivalent to the Task Force Monitor 3040 (K014063) and ZOLL M-Series NIBP Option (k032363)
Device description:	The CNAP™ Monitor 500 is a device for continuous non-invasive blood pressure monitoring. The device measures continuous and oscillometric blood pressure as well as pulse rate. CNAP is a joint solution, where absolute blood pressure values are coming from an integrated OEM oscillometric blood pressure device and beat-to-beat changes as well as waveform are measured with the CNAP finger sensor. Finger-BP is automatically calibrated to absolute NIBP-values. Immediately after a NIBP, the CNAP-computer puts systolic and diastolic finger BP on the same level as NIBP values. NIBP calibrations can be obtained ipsilateral as well as contralateral to the CNAP-cuff.
Intended use:	The CNAP Monitor 500 is intended for the monitoring of non-invasive continuous blood pressure and pulse rate in hospitals, clinical institutions, medical practices and outpatient settings. The device displays the blood pressure waveform and generates trends, beat-to-beat numerics and alarms for the parameters blood pressure and pulse rate. The CNAP Monitor 500 is to be used for adults and pediatric patients from the age of 4 year and is to be operated by physicians and other medical professional staff.
Technology:	The device employs the same functional technology as its predicate device.
Functional/Safety Testing:	The CNAP Monitor 500 has successfully undergone safety testing as well as functional testing to demonstrate equivalence to its predicate device. The following quality assurance measures were applied to the device: - Risk Analysis - Requirements Review - Code inspections - Verification and Validation - Bench Testing (for continuous blood pressure measurement functionality) - Clinical Performance Testing (for oscillometric NIBP measurement functionality) - Biocompatibility Testing - Safety Testing (CB Test Protocol)

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Medizintechnik GmbH

Conclusion:	The results of this testing demonstrates that the device is safe and effective and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 17 2008

TUV SUD American Inc.
c/o Mr. Norbert Stuiber
Third Party Reviewer
1775 Old Highway 8 NW, Ste. 104
New Brighton, MN 55112-1891

Re: K082599
Trade/Device Name: CNAP Monitor 500i, 500at
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 26, 2008
Received: October 3, 2008

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part

807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082599

Indications for Use

510(k) Number (if known): K082599

Device Name: CNAP Monitor 500i, 500at

Indications For Use:

The CNAP Monitor 500 is intended for the monitoring of non-invasive continuous blood pressure and pulse rate in hospitals, clinical institutions, medical practices and outpatient settings. The device displays the blood pressure waveform and generates trends, beat-to-beat numerics and alarms for the parameters blood pressure and pulse rate. The CNAP Monitor 500 is to be used for adults and pediatric patients from the age of 4 year and is to be operated by physicians and other medical professional staff.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082599